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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,617	09/19/2000	Kuniki Kino	506.39084X00	5296

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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/665,617

Applicant(s)

KINO ET AL.

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-10 is/are pending in the application.
4a) Of the above claim(s) 6-10 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 is/are rejected.
7) ☒ Claim(s) 5 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

Art Unit: 1651

The amendment filed 9/11/03 is acknowledged. Claims 3 are being considered on the merits.

Claims 6-10 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of histidine with strains derived from *Escherichia coli* FERM-BP-6673, does not reasonably provide enablement for the production of this amino acid with any *Escherichia coli* resistant to 150 mg/l of primaquine or alkali metal salts thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

From the record of the present written disclosure and the Abe Declaration, offsprings of strain *E. coli* H-9340 are shown to be capable of the production and accumulation of the required product. While essentially any strain of *Escherichia coli* has an ability to produce L-histidine, there is nothing on this record to show or suggest that resistance to primaquine in the claimed amount is sufficient to cause L-histidine to accumulate in the culture medium, as claimed.

It would require undue experimentation for one skilled in the art to determine which other strains of *Escherichia coli* would be suitable for the claimed invention, in view of the diversity of strains encompassed. It is noted that a specific strain of *E. coli* was mutagenized by random mutagenesis in order to obtain the parent histidine producing strain having the required capability. As correctly indicated by Applicants, "there are complicated regulation system in the biosynthesis pathway for amino acids" (previous response, page 6 and references cited therein). Moreover, this record provides no clear correlation between resistance to 150 mg/l of primaquine for any strain of *Escherichia coli* and the production and accumulation of histidine as required.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation to screen and select *Escherichia coli* strains that will be capable of

Art Unit: 1651

producing histidine upon resistance to 150 mg/l of primaquine; limited amount of guidance and limited number of working examples in the specification related to this screening and selection process to show the requisite correlation thereof; the unpredictable nature of the invention; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

Response to Arguments

Applicant's arguments and the Abe declaration have been fully considered but they are not deemed to be persuasive.

The Abe declaration refers to Example 1 of the specification, wherein strain H-9340, deposited as FERM BP-6673, resistant to 1,2,4, triazole alanine is obtained from strain ATCC 21318, . This strain is further mutagenized and selected to obtain strains according to the claimed invention. The declaration does not address the unpredictability of obtaining histidine accumulating strains of *E. coli* merely by assessing their resistance to 150 mg/l of primaquine or alkali metal salts thereof.

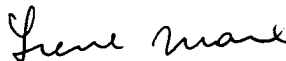
Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.



Irene Marx
Primary Examiner